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Protocol for an Experiment on Controlling Motion Sickness Severity in a Ship Motion Simulator

J.L. Colwell

Defence R&D Canada – Atlantic

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This protocol defines a human performance experiment to assess the feasibility of controlling the motions of a ship motion simulator (SMS) to achieve a moderate severity of motion sickness, which is sustainable for a substantial time. For this experiment, motion sickness severity is assessed by both the subject and experimenter, and the definition of substantial time is bounded by the two-hour duration of each subject's exposure to motions in the SMS. The secondary goals of this experiment are to examine methods for assessing the effects of moderate levels of motion sickness severity on: (i) the reliability of subjective assessment of task duration, (ii) the reliability of subjective assessment of problems performing cognitive tasks; and, (iii) to explore techniques for assessing problems with complex decision making.

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DRDC Atlantic TM 2004-282

October 2004

Author

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Approved By

Neil Pegg

Head, Warship Performance Section

Chair

DRP

Human subjects

This study, approved by the DRDC Toronto Human Research Ethics Committee, was conducted in conformity with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

Abstract

This protocol defines a human performance experiment to assess the feasibility of controlling the motions of a ship motion simulator (SMS) to achieve a moderate severity of motion sickness, which is sustainable for a substantial time. For this experiment, motion sickness severity is assessed by both the subject and experimenter, and the definition of substantial time is bounded by the two-hour duration of each subject's exposure to motions in the SMS. The secondary goals of this experiment are to examine methods for assessing the effects of moderate levels of motion sickness severity on: (i) the reliability of subjective assessment of task duration, (ii) the reliability of subjective assessment of problems performing cognitive tasks; and, (iii) to explore techniques for assessing problems with complex decision making.

Résumé

Le protocole définit une expérience sur le rendement humain visant à évaluer la possibilité de maîtriser les mouvements d'un simulateur des mouvements d'un navire afin d'engendrer un mal des transports d'intensité modérée tolérable pendant une assez longue période. Pour cette expérience, l'intensité du mal des transports est évaluée par le sujet et par l'expérimentateur, et la définition d'une assez longue période est limitée par la période de deux heures à laquelle chaque sujet est exposé aux mouvements dans le simulateur. Les objectifs secondaires de l'expérience sont d'examiner des méthodes qui permettraient d'évaluer les effets du mal des transports d'intensité modérée sur (i) la fiabilité de l'évaluation subjective de la durée de la tâche et (ii) la fiabilité de l'évaluation subjective des problèmes lors de l'exécution de tâches cognitives ainsi que (iii) d'examiner des techniques pour évaluer les problèmes liés à la prise de décisions complexes.

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Executive Summary

Introduction

All experiments involving the use of human subjects which are performed or sponsored by DRDC agencies must be reviewed and approved by the DRDC Toronto Human Research Ethics Committee (HREC). This particular experiment protocol was developed to assess the feasibility of controlling the motions of a land-based ship motion simulator (SMS) to achieve a moderate severity of motion sickness, which is sustainable for a substantial time. This type of SMS produces real motions which represent simulated ship and sea conditions. The primary purpose for this Technical Memorandum is to document the protocol as approved by HREC.

Results

This protocol was first reviewed by HREC on 5 October 2004, and received final approval on 31 October 2004. The experiment was performed in November 2004 by the Centre for Marine Simulation, of the Memorial University of Newfoundland, under contract to DRDC Atlantic. Results of the experiment itself will be published in future documents.

Significance

The development of an acceptable protocol is a critical step in performing an experiment involving human subjects. The protocol outlines the reasons for seeking to perform such an experiment, and has a strong emphasis on describing experiment procedures and risk mitigation strategies which are appropriate and necessary to ensure the safety and integrity of all participants.

Future Plans

This experiment protocol may be an important step towards developing a new methodology for examining ship motion effects on human performance in land-based motion simulators; however, any conclusions on the merit of this approach and possible future developments must await the analysis and reporting of experiment results.

Colwell, J.L. 2004. Protocol for an Experiment on Controlling Motion Sickness Severity in a Ship Motion Simulator. DRDC Atlantic TM 2004-282.

Sommaire

Introduction

Toutes les expériences auxquelles participent des sujets humains qui sont menées ou parrainées par des organismes de RDDC doivent être revues et approuvées par le Comité d'éthique en matière d'étude sur des sujets humains (CEESH) de RDDC Toronto. Le protocole expérimental dont il est question a été élaboré en vue d'évaluer la possibilité de maîtriser les mouvements d'un simulateur terrestre des mouvements d'un navire afin d'engendrer un mal des transports d'intensité modérée tolérable pendant une assez longue période. Ce type de simulateur produit des mouvements réels qui simulent les conditions sur des navires en mer. L'objectif premier du présent document technique est de présenter le protocole tel qu'il a été approuvé par le CEESH.

Résultats

Le protocole a été examiné pour le première fois par le CEESH le 5 octobre 2004 et a été approuvé le 31 octobre 2004. L'expérience a été menée en novembre 2004 par le Centre for Marine Simulation de l'Université Memorial de Terre-Neuve, dans le cadre d'un contrat avec RDDC Atlantique. Les résultats de l'expérience seront publiés dans d'autres documents.

Portée

L'élaboration d'un protocole acceptable est une étape essentielle d'une expérience menée sur des sujets humains. Le protocole définit les raisons d'une telle expérience et décrit de façon approfondie les méthodes expérimentales et les stratégies d'atténuation du risque indiquées et nécessaires pour garantir la sécurité et l'intégrité de tous les participants.

Plans pour l'avenir

Le protocole expérimental pourrait constituer une étape importante vers la mise au point d'une nouvelle méthode qui permettrait d'examiner les effets des mouvements des navires sur le rendement humain dans des simulateurs terrestres de mouvements. Toutefois, aucune conclusion sur la valeur de cette méthode et les possibilités de développement dans l'avenir ne peut être tirée avant l'analyse des résultats expérimentaux et la présentation du rapport.

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Acknowledgements

The author wishes to thank Mr. Peter van Terwisga, of the Royal Netherlands Navy, for raising the following question during a recent meeting of the ABCD Working Group on Human Performance at Sea[1]: "*why not control motions for constant motion sickness ?*" Perhaps this experiment will provide some answers. The author also wishes to thank Dr. Scott MacKinnon at the Memorial University of Newfoundland (MUN) School of Human Kinetics and Recreation, and Mr. Anthony Patterson and Mr. Carl Harris at the MUN Centre for Marine Simulation (CMS), for their assistance in preparing for and conducting this experiment at the CMS ship motion simulator.

Preface

This Technical Memorandum documents an experiment protocol approved by the DRDC Toronto Human Research Ethics Committee (HREC) for a human performance experiment performed at the Memorial University of Newfoundland in November 2004. This protocol was first reviewed by HREC on 5 October 2004, and received final approval of HREC on 31 October, 2004. The protocol format has been modified to conform with the general DRDC Technical Memorandum document layout; however, the required structure and sequence of a DRDC Toronto protocol is preserved.

[1] The ABCD Working Group on Human Performance at Sea is an informal association of American, Australian, British, Canadian, and Dutch organizations with a common interest in the effects of ship motions on human performance in the naval environment.

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1 Introduction (Protocol Executive Summary)

Protocol # L-480

Title: Controlling Motion Sickness Severity in a Ship Motion Simulator

Principal Investigator: *S.N. MacKinnon, PhD, Assistant Professor and Director of the Human Performance in Harsh Environments Laboratory, School of Human Kinetics and Recreation, Memorial University of Newfoundland (MUN)*

Co-Investigator: *J.L. Colwell, Defence Scientist, Warship Performance, DRDC Atlantic*

Project: 11GK15 - Human Performance

During a major NATO exercise in 1997, approximately one-half of 1025 naval subjects reported mild and moderate motion sickness (MS) symptoms for sustained periods of time during operations in high seas, while the other half did not report any motion sickness symptoms at all. Those subjects in the group with mild and moderate MS symptoms reported substantially higher severity of problems with cognitive and physical performance, and with task completion than those with no MS symptoms. Since these results were obtained using self-administered questionnaires, it is important to validate the reliability of this approach in a controlled experiment; however, in virtually all land-based ship motion simulator (SMS) experiments, the SMS motions are either held constant or varied according to a time-fixed pattern. This approach provides a well-controlled and repeatable procedure for varying the independent variable (i.e. motion), but it is not suitable for examining the effects of sustained mild and moderate MS symptoms on performance.

The primary goal of this experiment is to assess the feasibility of controlling the motions of a ship motion simulator (SMS) to achieve a *moderate* severity of motion sickness, which is sustainable for a *substantial* time. For this experiment, motion sickness severity is assessed by both the subject and experimenter, as described in the protocol, and the definition of *substantial* time is bounded by the two-hour duration of each subject's exposure to motions in the SMS. The secondary goals of this experiment are to examine methods for assessing the effects of moderate levels of motion sickness severity on: (i) the reliability of subjective assessment of task duration, (ii) the reliability of subjective assessment of problems performing cognitive tasks; and, (iii) to explore techniques for assessing problems with complex decision making.

The potential risks to subjects are confined to experiencing a range of MS symptoms from stomach awareness to nausea and possibly vomiting; however, the experiment seeks to avoid nausea and vomiting. The ship motion simulator being used for the experiment dynamic runs has both software and hardware safety interlocks to prevent loss of control and to avoid excessive motions. This facility is ISO 9001 certified, and it has a safe operating history of over ten years use as a motion platform for maritime certification programmes delivered by the Marine Institute of MUN.

This experiment protocol is being submitted for concurrent approval by the MUN Human Investigation Committee. This experiment will be performed by the Marine Institute of MUN, under a research contract with DRDC Atlantic.

2 Ethics Review

This experiment protocol is subject to concurrent review by both the DRDC Toronto Human Research Ethics Committee (HREC) and the Memorial University of Newfoundland (MUN) Human Investigation Committee (HIC). The ethical guidelines for humans participating in scientific research of both HREC and HIC are based on and conform to the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans [1]. The HIC process is described at the MUN Faculty of Medicine web site for HIC (www.med.mun.ca/hic). Required supplemental information attached as annexes to this protocol include: Annex A, subject recruitment poster; Annex B, subject consent form; Annex C, questionnaire on pregnancy and vestibular problems; Annex D, physical fitness evaluation questionnaire; Annex E, motion sickness susceptibility questionnaire; and, Annex F, symptomatology and performance questionnaire. These annexes are described in more detail in following sections of this submission to HREC.

3 Background

During a major NATO exercise in 1997 [2], approximately one-half of 1025 naval subjects reported mild and moderate motion sickness (MS) symptoms for sustained periods of time during operations in high seas, while the other half did not report any motion sickness symptoms at all. Those subjects in the group with mild and moderate MS symptoms reported substantially higher severity of problems with cognitive and physical performance, and with task completion than those with no MS symptoms. The types of problems reported and the potential consequences in terms of reduced naval effectiveness were sufficiently serious that these trends should be investigated in more depth [3]. Since these results were obtained using self-administered questionnaires, it is important to validate the reliability of this approach. This is particularly true for certain questions which rely on subjective interpretation of the person's well being and qualitative performance effects, such as the subject "made more mistakes than usual", and "tasks took longer than usual" to complete.

In virtually all land-based ship motion simulator (SMS) experiments, the SMS motions are held constant or varied according to a time-fixed pattern. This approach provides a well-controlled and repeatable procedure for varying the independent variable (i.e. motion), but it is very difficult to obtain and sustain mild and moderate levels of MS severity in the experiment subjects. The typical response of subjects who are at least somewhat susceptible to MS varies according to how 'provocative' the motions are, and how long the subjects are exposed to the motions. When a *moderately* provocative, constant motion environment is produced in an SMS, then the severity of MS symptoms for any particular subject generally increases over time. If the experiment is of fixed

duration, say one or two hours, then some subjects will likely get so sick that they will abandon the experiment (either voluntarily or by decision of an independent observer), and the remainder will experience some mix of symptom severity varying from mild through to severe. Once an individual begins to experience MS symptoms, the severity of the symptoms tends to accelerate rapidly or 'avalanche' [4] from the milder, precursor symptoms of 'stomach awareness' through to the more severe symptoms of nausea and vomiting (and consequent abandonment of the experiment). Thus, it is very difficult to examine the effects of sustained mild and moderate MS severity on human performance in a traditional SMS experiment.

In this proposed new experiment, the primary dependent variable is MS severity, but its amplitude will be used as feedback to modify the primary independent variable, the ocean wave height used to derive the SMS motions. In this sense, the experiment does not truly have independent and dependent variables; rather, they are interdependent. The main goal is to determine if MS severity can be controlled using this approach; if it can be controlled, then future SMS experiments can be devised with MS severity as the independent variable, and various performance metrics as the dependent variables.

The feedback between MS severity and SMS motions will be very simple: when MS severity exceeds a certain maximum threshold value, then the motions will be made 'less provocative'; and, when the MS severity falls below a certain minimum threshold value, the motions will be made 'more provocative'. Previous work has established that it is possible to avoid the more severe symptoms of motion sickness by adjusting the strength and duration of the provocative stimulus [4,5], but this reduction of stimulus generally coincides with the end of the experiment. For the proposed new experiment, the first reduction in motion stimulus to avoid more severe MS symptoms represents the starting point - the challenge is to determine if MS severity can be sustained at moderate levels, and neither dissipate to insignificant levels, nor escalate to severe levels and premature termination of the experiment.

4 Purpose of Study

The primary goal of this experiment is to assess the feasibility of controlling the motions of a ship motion simulator (SMS) to achieve a *moderate* severity of motion sickness, which is sustainable for a *substantial* time. For this experiment, motion sickness severity is assessed by both the subject and experimenter, as described on pages 7 and 8 of this protocol, and the definition of *substantial* time is bounded by the two-hour duration of each subject's exposure to motions in the SMS. It is hoped that a moderate severity of motion sickness can be achieved during or shortly after an initial exposure phase of thirty minutes, and then sustained at or near the same level of severity for the remainder of the two hour exposure.

The secondary goals of this experiment are to examine methods for assessing the effects of moderate levels of motion sickness severity on: (i) the reliability of subjective

assessment of task duration, (ii) the reliability of subjective assessment of problems performing cognitive tasks; and, (iii) to explore techniques for assessing problems with complex decision making.

5 Selection of Human Subjects

Eighteen healthy male and female volunteers will be recruited from the general public and, in particular, from the student population at the Memorial University of Newfoundland, using posters as shown in Annex A. Subjects will be given a written copy of this protocol and a verbal explanation of the experiment, including: the expectations of the subject; the roles of the investigator and observer; and, the subject's right to voluntarily withdraw from the experiment at any time. Subjects who agree to participate will be required to read, understand, discuss and agree with the subject consent form shown in Annex B, and to signify this agreement by signing that form.

Females who are currently pregnant, individuals with heart or respiratory illness, and individuals with vestibular system (or balance organ) problems may not participate in the experiment. All potential subjects will complete the questionnaire on pregnancy and vestibular problems in Annex C and the Physical Activity Readiness Questionnaire (PAR-Q) in Annex D. Any individuals who answer yes to any one or more of the questions in Annexes C and D will be disqualified from participating in the experiment.

Possible effects on the fetus from this type of study are unknown. Therefore, if a woman cannot rule out pregnancy, she must be excluded from participating as a subject. Female subjects are required to take appropriate precautions to prevent pregnancy for the duration of the entire experiment, and are cautioned that the only absolute method of preventing pregnancy is abstinence of sexual intercourse.

The motion sickness susceptibility questionnaire shown in Annex E [8] will be used to evaluate potential subjects. Individuals who are highly resistant to MS will not be selected for this experiment. Subjects will be requested to abstain from taking any alcohol or medication, including cold medication with antihistamines, within 24 hours of the experiment.

All experimental data will be kept private and confidential. Data and analysed results for particular individual subjects will be identified using coded study numbers, and these study numbers will be stored separately from the data and analysed results. Access to the actual identities of study participants will be limited to the principal and co-investigators. The data will be held indefinitely in archival storage at MUN. The principal investigator will be data guardian.

6 Methodology

This experiment will be performed by the Marine Institute of MUN, under a research contract with DRDC Atlantic.

Dr. S.N. MacKinnon, Director of the Human Performance in Harsh Environments Laboratory, School of Human Kinetics and Recreation, MUN, will be the Principal Investigator.

The experiment will be performed in the Full Mission Ship Bridge Simulator of the Centre for Marine Simulation, at the Marine Institute of MUN. This facility is a large ship bridge (5m x 7m), mounted on a six degrees of freedom ship motion simulator (SMS) motion base, and surrounded by 360° azimuth coverage by visual projection screens.

The SMS produces real motions for a simulated ship in a simulated environment. The key variables are the size and shape of the hull, the ship speed and course, the ocean wave height, wave period (or wave length) and wave direction. All of these variables are used as input to the calculation procedure which produces the simulator motions. In general, human motion sickness response to ship motions is related to the duration of exposure to the motions, the amplitude of the motions and the frequency of the motions [9,10]. The motions for the experiment will be developed for a relative wave direction of approximately 45° off the bow, and with a frequency of vertical motion of approximately 0.2 Hz, which corresponds to the peak in human sensitivity to motion sickness for vertical sinusoidal motion [9,10]. The amplitude of the simulated ship motions will be adjusted by adjusting the simulated wave height, which provides control over how 'provocative' the motions are for motion sickness.

The experiment will not require the taking of any blood, fluid or body tissue samples, nor the use of any invasive medical procedures.

6.1 Experiment protocol

Each of the eighteen subjects will perform the two-hour protocol on two occasions; once in a dynamic environment with motion provided by the Ship Motion Simulator (SMS), and a second time in a static environment, with no motions. The experiment will be performed over two consecutive weeks, with each subject being tested once in each week. In the first week, one-half of the 18 subjects will be randomly selected to undergo dynamic tests and the others will undergo the static tests. On the second week, subjects will experience the condition not done in the first week.

During the two-hour dynamic test, the severity of SMS motions is determined by the severity of the subject's motion sickness (MS), as described below. The maximum motion environment can be characterized as having the following maximum peak amplitudes: pitch angle up to 10°, heave displacement up to 0.8 m (with pitch-up

coinciding with heave-up), and roll angle up to 14°; with motion frequencies for pitch, heave and roll varying between approximately 0.10 and 0.25 Hz

Subjects in the SMS dynamic runs will be seated and facing forward. Subjects will be requested to minimize head movements and to keep their gaze fixed on the computer screen on the desk in front of them. One subject will be tested at a time. The interior of the SMS will be fully illuminated and the exterior will be dark, and no external visual displays will be used. At any time, the subject can terminate the experiment at a single request to do so.

During the experiment test runs, the subject will perform a variety of questionnaire completions and computer-based cognitive tests. The key consideration for timing and synchronization within the test protocol is the following schedule for questionnaire completions. The actual questionnaires being completed are described in the next section.

1. Every ten minutes, starting at 'time zero' and continuing throughout the two hour experiment duration, the subject will be verbally requested to define the severity of their MS symptoms, using a simple eleven-point scale (i.e. zero to 10), as described in the next section.

2. At the end of the first hour, and again at the end of the second hour, the subject will complete a pen/paper version of the Symptoms and Performance sections of the NATO Questionnaire [2,3], as shown in Annex F. It will usually take only two or three minutes to complete this questionnaire. The second completion of this questionnaire defines the end of the test for both the dynamic and static conditions. For the dynamic tests, the SMS motions will not be changed (i.e. turned off) until after this questionnaire is completed, even though the total elapsed time since the start of the run may exceed two hours by a few minutes.

During the ten minute interval between making MS severity reports, the subject will perform a variety of computer-based tasks, which are primarily simple cognitive tests, as described later. The same sequence of tasks is used each time, and it is devised to take about five minutes to complete for a typical subject with no MS symptoms.

6.2 Interdependence of variables

The severity of the SMS motions will be controlled according to the severity of the subject's MS symptomatology: if the subject is too sick, then SMS motions will be reduced; and, if the subject is too well, then the SMS motions will be increased. Time delays will be incorporated to allow for the normal onset of MS during an initial exposure phase, and to avoid sequential increases or reductions in motion before the subject's change in MS severity due to the previous change in motions can be expressed.

6.3 Assessing MS Severity

The overall approach used to assess MS severity for this experiment follows Reason and Diaz (1971) [4,11], which used two independent measures of the subject's MS severity:

1. subjective self-assessment of MS severity reported by the subject; and,
2. objective assessment of MS severity reported by the experimenter.

6.3.1 MS symptoms: subjective self-assessment

The Misery Scale, or MISC [6,7], shown in Table 1 is used for subjective assessment of MS severity. The subject will provide a verbal MISC score every ten minutes, in response to a verbal request from the experimenter. In this way, the experimenter controls the timing of MISC score reporting, and also receives immediate feedback on the subject's self-assessment of their current MS state. The subject will also be advised at the start of the experiment that they should immediately notify the experimenter at any time if they feel that they have advanced into the more severe MS symptoms, and the experimenter will respond by reducing the SMS motions.

The desired level of MS severity to be sustained in this experiment is defined as scores of 4 or 5 on the MISC scale. Lower scores of 2 or 3 on the MISC scale show that the subject is probably experiencing mild symptoms of MS (which is within the scope of interest for this experiment), and one would expect that MS severity would increase for this subject over time, especially if the motions are made more provocative. Higher MISC scores of 6 and 7 suggest that the subject is progressing towards severe levels of MS, and that the SMS motions should be reduced.

Table 1: MISC scale [6,7] for subjective assessment of MS severity.

Symptom		score
No problems		0
Uneasiness (no typical symptoms)		1
Dizziness, warmth, headache, stomach awareness, sweating, ...	vague	2
	slight	3
	fairly	4
	severe	5
Nausea	slight	6
	fairly	7
	severe	8
	(near) retching	9
Vomiting		10

6.3.2 MS signs: observed by experimenter

The experimenter will use the checklist shown in Table 2 to rate the severity of the subject's signs of MS. The experimenter will complete this checklist every ten minutes throughout the experiment, immediately before asking the subject to score MS severity on the MISC scale. In this way, the experimenter's assessment of MS signs will not be influenced by the subject's perception of MS symptoms, and the subject's and observer's assessments of MS severity will always be closely synchronized in time. The experimenter will also have to be vigilant to detect a possible rapid onset or avalanche [4] of increasingly severe MS in the subject and respond by immediately reducing the SMS motions.

Table 2: Observer checklist score (OCS) of MS signs

Observer Checklist Score (OCS)				
0 = none, 3 = severe:	0	1	2	3
pallor	☐	☐	☐	☐
cold sweat	☐	☐	☐	☐
salivation	☐	☐	☐	☐
swallowing	☐	☐	☐	☐
increased breathing rate	☐	☐	☐	☐
yawning	☐	☐	☐	☐
belching	☐	☐	☐	☐

6.4 Criteria for changing SMS motions

The following criteria will be used as MS severity thresholds for motion control. MISC is the subjective MS severity score from Table 1, and OCS is the Observer Checklist Score from Table 2.

1) reduce SMS motions if

   (a) MISC > 5, or
   (b) MISC > 4 and OCS > 2 for any single parameter in Table 2

2) increase SMS motions if

   (a) MISC < 3, or
   (b) MISC < 4 and OCS < 2 for all parameters in Table 2

As discussed earlier, changes to SMS motions will be controlled by changing the significant wave height, H_S, being used for the SMS 'internal model'. SMS motions are reduced by reducing the wave height by 50%, and motions are increased by increasing wave height by 25%. Thus, a relatively aggressive approach is taken to reduce MS severity, and a more gradual approach is taken to increase MS severity.

6.5 Performance tests

During the experiment, the subject will perform a sequence of the following computer-based cognitive performance tests from the DRDC Toronto Sustained Operations (Susops6) package: Addition (ADD); Detect Repeat Number (DRN); Logical Reasoning (LRT); Serial Reaction Time (SRT); and, Short Term Memory (STM). The test sequence begins immediately after each subject reports their current MS severity (i.e. every ten minutes), and continues for approximately five minutes.

6.6 Data analysis

The feasibility of controlling motion sickness severity by controlling the severity of SMS motions will be assessed by considering the proportion of subjects for which this could be achieved. Data analysis to support secondary objectives regarding the reliability of subjective assessment of time and task performance effects will be evaluated using repeated-measures ANOVA.

6.7 Medical screening

Females who are currently pregnant, individuals with heart or respiratory illness, and individuals with vestibular system (or balance organ) problems may not participate in the experiment. All potential subjects will complete the questionnaire on pregnancy and vestibular problems in Annex C and the Physical Activity Readiness Questionnaire (PAR-Q) in Annex D. Any individuals who answer yes to any one or more of the questions in Annexes C and D will be disqualified from participating in the experiment. In the absence of a physician, the principal investigator or a medical support person will administer the questionnaires.

6.8 Physician coverage

Physician coverage is not required as this is a low risk study.

6.9 Supervising experimental runs

The experimenter, who is either the principal investigator or his designate, Mr. Jon Power, will be present in the SMS with the subject at all times. The experimenter will assist the needs and security of the subject and if in the best interest of the subject, will recommend termination of the protocol. Additionally, the experiment will be monitored on closed-circuit video by an independent SMS operator who is located in an external control room. In order to avoid possible problems with sickness of the experimenter, the SMS operator will be instructed to be vigilant for signs of severe nausea or imminent vomiting in the experimenter, and to end the experiment run if this occurs.

7 Risks and Safety Recommendations

The potential risks to subjects are confined to experiencing a range of MS symptoms from mild stomach awareness to severe nausea and possibly vomiting.

It is possible that subjects who experience severe motion sickness (which the experiment seeks to avoid) may experience post-experiment after-effects of motion sickness and so should not operate a vehicle - any subjects who experience severe motion sickness will be provided transportation to their home.

The ship motion simulator being used for the experiment has both software and hardware safety interlocks to prevent loss of control and to avoid excessive motions. This facility is ISO 9001 certified, and it has a safe operating history of over ten years use as a motion platform for maritime certification programmes delivered by the Marine Institute at MUN. Also, a number of human research experiments have been performed in this facility since 2002, all of which have been submitted to and approved by the MUN Human Investigation Committee.

8 Benefits of Study

Naval ship crews continue to diminish in size and their tasks continue to increase in complexity. Thus, the need to identify, understand and quantify sources of human performance degradation is becoming critical. If successful, this experiment will enable experimenters to use motion sickness severity as an independent variable, and measures of task performance as dependent variables.

Individual subjects who are highly susceptible to motion sickness may develop strategies to mediate these effects by participating in this experiment.

9 Approximate Time Involvement

The total time involvement for a subject who fully participates in the experiment will be approximately five hours over two weeks, with four hours actually performing the experiment protocol on two separate occasions, plus approximately one additional half-hour on each of the two visits for experiment startup and completion.

10 Remuneration

Subjects will not be paid to participate in this experiment; however, reasonable expenses incurred to enable participation will be reimbursed upon submission of receipts.

11 Concluding Remarks

This concludes the main body of the DRDC protocol, as approved by the DRDC Toronto Human Research Ethics Committee (HREC). Remaining sections contain the References, Acronyms and Abbreviations, and Annexes of the approved protocol.

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Acronyms and Abbreviations

ANOVA ..... analysis of variance, a statistical method
DRDC ..... Defence R&D Canada
HIC ..... Human Investigation Committee, MUN human research ethics committee
HREC ..... Human Research Ethics Committee, DRDC Toronto
ISO ..... International Standards Organization
MISC ..... Misery Scale [6,7]
MS ..... motion sickness
MUN ..... Memorial University of Newfoundland
NATO ..... North Atlantic Treaty Organization
OCS ..... Observer Checklist Score (experimenter's assessment of MS severity)
PAR-Q ..... Physical Activity Readiness Questionnaire, www.csep.ca/pdfs/par-q.pdf
SMS ..... Ship Motion Simulator

Annex A: Subject Recruitment Poster

Want to participate in a research study?

Volunteers are needed for a study that will evaluate how moderate levels of motion sickness affects cognitive performance.

- Contribute to our understanding of motion sickness and its prevention.

Who can participate?

- Anyone between 19-55 years of age.
- Healthy individuals who are not on regular medications

Who cannot participate?

- Females currently pregnant
- Anyone with current heart or respiratory illnesses
- Anyone with balance or vestibular problems

Experiment procedure You will spend two hours in the Marine Institute ship motion simulator on each of two visits; on one visit the simulator will be moving like a ship at sea, and on the other visit it will not be moving. During the two hours, you will perform a variety of cognitive computer tests, and every ten minutes you will tell us how you feel. If you have any symptoms of motion sickness worse than "stomach discomfort", such as "mild nausea", we will reduce the simulator motions. If you don't have any symptoms of motion sickness at all, then we will increase the simulator motions. The whole point of the experiment is to see if we can keep your motion sickness symptoms to "low" and "moderate" levels during the two hours.

Duration of subject participation We need about 5 hours of your time for performing the experiment in the simulator, plus about one more hour before the experiment for an interview. The first visit to the simulator will be in the week of 1 November and the next visit will be about one week later - we'll let you know the exact schedule in plenty of time.

Possible risks There is a small risk that you might experience severe levels of nausea and possibly even vomit, but we'll do our best to avoid that.

To find out more, contact:

Scott MacKinnon, School of Human Kinetics and Recreation
737-8807 or smackinn@mun.ca

Annex B: Subject Consent Form

VOLUNTARY CONSENT FORM FOR HUMAN SUBJECT PARTICIPATION

Protocol Number: L-480
Research Project Title: Controlling Motion Sickness Severity in a Ship Motion Simulator

Principal Investigator: Dr. Scott N. MacKinnon, MUN, (709) 737-8807
Co-investigator: Mr. James L. Colwell, DRDC Atlantic, (902) 426-3100

I, _____ (name)

of _____ (address and phone number)

hereby volunteer to participate as a subject in the study, "Controlling Motion Sickness Severity in a Ship Motion Simulator". I have read the information package on the research protocol, and have had the opportunity to ask questions of the Investigator. All of my questions concerning this study have been fully answered to my satisfaction. However, I may obtain additional information about the research project and have any questions about this study answered by contacting Dr. Scott N. MacKinnon at (709) 737-8807, or Mr. James L. Colwell at (902) 426-3100 ext. 125.

I have been told that I will be asked to participate in two sessions each of approximately two hours duration and that I must not take any alcohol or medication, including cold medication with antihistamines, within 24 hours of the experiment. To the best of my knowledge I am not aware that I have any abnormal vestibular (balance organ) problems.

I have been told that the principal risks of the research protocol are experiencing a range of MS symptoms from stomach awareness to nausea and possibly vomiting.

I have been given examples of potential minor and remote risks associated with the experiment and consider these risks acceptable as well. Also, I acknowledge that my participation in this study, or indeed any research, may involve risks that are currently unforeseen by DRDC Toronto.

I have been advised that the following medical support will apply during the experiment: on site first aid.

I hereby consent to the medical screening assessment outlined in the protocol and agree to provide responses to questions that are to the best of my knowledge, truthful and complete. Furthermore, I agree to advise the Investigator of any health status changes since my initial assessment (including, but not limited to, viral illnesses, new prescription or 'over-the-counter' medications, and new risk of pregnancy). I have been advised that the medical information I reveal and the experimental data concerning me will be treated as confidential, and not revealed to anyone other than the Investigator without my consent except as data unidentified as to source. Moreover, should it be required, I agree to allow the experimental data to be reviewed by an internal or external audit committee with the understanding that any summary information resulting from such a review will not identify me personally. In the highly unlikely event that I become incapacitated during my participation, I understand that every necessary medical treatment will be instituted even though I am unable to give my consent at that time. I will go with the Investigator to seek immediate medical attention if either the Investigator or I consider that it is required. Every effort will be made to contact a family member or the designated person indicated below should that be necessary.

For female subjects: To the best of my knowledge, I am not pregnant. Furthermore, I have no reason to suspect I might be pregnant. I understand that this information and all discussion pertaining to this matter will be treated as confidential. If I have any concern regarding a possible pregnancy, I will consult a physician before undertaking or resuming any phase of the experiment. Furthermore, I will take appropriate precautions to prevent pregnancy for the duration of the entire experiment. Moreover, I understand that the only absolute method of preventing pregnancy is abstinence of sexual intercourse.

I understand that I am free to refuse to participate and may withdraw my consent without prejudice or hard feelings at any time. Should I withdraw my consent, my participation as a subject will cease immediately, unless the Investigator determines that such action would be dangerous or impossible (in which case my participation will cease as soon as it is safe to do so). I also understand that the Investigator or their designate may terminate my participation at any time, regardless of my wishes.

I understand that by signing this consent form I have not waived any legal rights I may have as a result of any harm to me occasioned by my participation in this research project beyond all risks I have assumed.

Volunteer's Name: _____

Signature: _____ Date: _____

Name of Witness to Signature: _____

Signature: _____ Date: _____

Certified fit to participate in this experiment as outlined in the research project.

Family Member or Contact Person (name, address, daytime phone number & relationship)

_____

Principal Investigator: Dr. Scott N. MacKinnon

Signature: _____ Date: _____

FOR SUBJECT ENQUIRY IF REQUIRED:

Should I have any questions or concern regarding this project before, during, or after participation, I understand that I am encouraged to contact any of the people listed below:

Principle Investigator:

Dr. Scott N. MacKinnon, (709) 737-8807 smackinn@mun.ca

Co-Investigator:

Mr. James L. Colwell, (902) 426-3100 ext 125 jim.colwell@drdc-rddc.gc.ca

Chair, DRDC Toronto Human Research Ethics Committee (HREC):

Dr. J.P. Landolt (416) 635 2104 jack.landolt@drdc-rddc.gc.ca

I understand that I will be given a copy of this consent form so that I may contact any of the above-mentioned individuals at some time in the future should that be required.

Annex C: Questionnaire on Pregnancy and Vestibular Problems

QUESTIONNAIRE ON PREGNANCY AND VESTIBULAR PROBLEMS

Protocol Number: L-480

Research Project Title: Controlling Motion Sickness Severity in a Ship Motion Simulator
Principal Investigator: Dr. Scott N. MacKinnon, MUN, (709) 737-8807
Co-investigator: Mr. James L. Colwell, DRDC Atlantic, (902) 426-3100

Females who are currently pregnant and individuals with vestibular system (or balance organ) problems may not participate in the experiment.

FOR FEMALES ONLY: PREGNANCY

1. Are you pregnant? Yes No

2. Is there a possibility that you are now pregnant? Yes No

Acceptable reasons for answering NO to the second question are: contraception by birth control pills, sexual abstinence, and menstruation within 1-2 weeks of experiment.

ALL SUBJECTS: VESTIBULAR PROBLEMS

1. Have you ever been diagnosed with or taken medications for labyrinthitis, vertigo, dizziness,
Meniere's disease or any other disease of the hearing or balance system? Yes No

2. Have you ever suffered a serious head injury? double vision? etc. Yes No

---

ALL SUBJECTS:

To the best of my knowledge, I have answered these questions truthfully.

Volunteer's Name _____

Signature: _____ Date: _____

Name of Witness to Signature: _____

Signature: _____ Date: _____

Principal Investigator: Dr. Scott N. MacKinnon

Signature: _____ Date: _____

Annex D: Physical Activity Readiness Questionnaire (PAR-Q) www.csep.ca/forms.asp (1/2)

Physical Activity Readiness Questionnaire - PAR-Q (revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO		
☐	☐	1.	**Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?**
☐	☐	2.	**Do you feel pain in your chest when you do physical activity?**
☐	☐	3.	**In the past month, have you had chest pain when you were not doing physical activity?**
☐	☐	4.	**Do you lose your balance because of dizziness or do you ever lose consciousness?**
☐	☐	5.	**Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?**
☐	☐	6.	**Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?**
☐	☐	7.	**Do you know of any other reason why you should not do physical activity?**

If you answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____ DATE _____

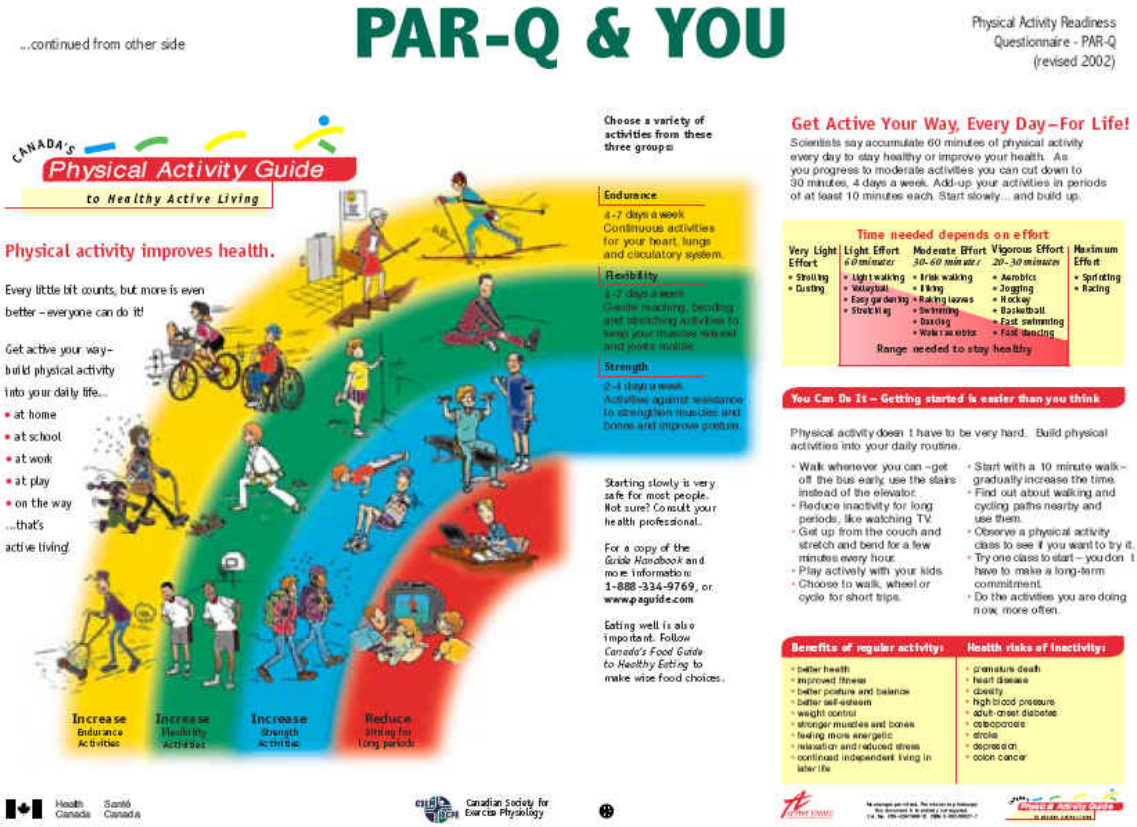
SIGNATURE OF PARENT or GUARDIAN (for participants under the age of majority) _____ WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

Supported by: Health Canada Santé Canada

continued on other side...

Annex D: Physical Activity Readiness Questionnaire (PAR-Q) www.csep.ca/forms.asp (2/2)



Source: Canada's Physical Activity Guide to Healthy Active Living, Health Canada, 1998 http://www.hc-sc.gc.ca/hppb/paguide/pdf/guideEng.pdf

FITNESS AND HEALTH PROFESSIONALS MAY BE INTERESTED IN THE INFORMATION BELOW:

The following companion forms are available for doctors' use by contacting the Canadian Society for Exercise Physiology (address below):

The **Physical Activity Readiness Medical Examination (PARmed-X)** – to be used by doctors with people who answer YES to one or more questions on the PAR-Q.

The **Physical Activity Readiness Medical Examination for Pregnancy (PARmed-X for Pregnancy)** – to be used by doctors with pregnant patients who wish to become more active.

References:

Arraix, G.A., Wigle, D.T., Mao, Y. (1992). Risk Assessment of Physical Activity and Physical Fitness in the Canada Health Survey Follow-Up Study. **J. Clin. Epidemiol.** 45:4 419-428.

Mottola, M., Wolfe, L.A. (1994). Active Living and Pregnancy. In: A. Quinney, L. Gauvin, T. Wall (eds.), **Toward Active Living: Proceedings of the International Conference on Physical Activity, Fitness and Health**. Champaign, IL: Human Kinetics.

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Thomas, S., Reading, J., Shephard, R.J. (1992). Revision of the Physical Activity Readiness Questionnaire (PAR-Q). **Can. J. Spt. Sci.** 17:4 338-345.

For more information, please contact the:

Canadian Society for Exercise Physiology
202-185 Somerset Street West
Ottawa, ON K2P 0J2
Tel. 1-877-651-3755 • FAX (613) 234-3565
Online: www.csep.ca

The original PAR-Q was developed by the British Columbia Ministry of Health. It has been revised by an Expert Advisory Committee of the Canadian Society for Exercise Physiology chaired by Dr. N. Gledhill (2002).

Disponible en français sous le titre «Questionnaire sur l'aptitude à l'activité physique - Q-AAP (revisé 2002)».

Supported by: Health Canada Santé Canada

Annex E: Motion Sickness Susceptibility Questionnaire

SHORT MOTION SICKNESS SUSCEPTIBILITY QUESTIONNAIRE [see Reference, below]

Please give your answers in words on the dotted lines, or encircle one of the printed options.

Date: . . . . . (dd/mm/yyyy)

Name: . . . . . .

Age: . . . . . year

Gender: male / female

Have you ever had any complaints regarding your ears? no / yes
If yes, what, ...
and at what age(s)? . . . . . year

Do you suffer from headaches? never / seldom / sometimes / often
If yes, did your physician characterize this as migraine? no / yes

The next questions refer to your sensitivity to motion sickness in the past, and to the kind of motions that you dislike most. Here, motion sickness refers to a clear feeling of discomfort, nausea, or vomiting due to motion.

How often did you feel sick ***as a child*** (below the age of 12 years) in

	t 0 1 2 3 .
cars	n.a. / never / seldom / sometimes / often
busses	n.a. / never / seldom / sometimes / often
trains	n.a. / never / seldom / sometimes / often
aircraft	n.a. / never / seldom / sometimes / often
small boats	n.a. / never / seldom / sometimes / often
large ships	n.a. / never / seldom / sometimes / often
swings	n.a. / never / seldom / sometimes / often
merry-go-rounds	n.a. / never / seldom / sometimes / often
leisure park attractions	n.a. / never / seldom / sometimes / often

Did you ever have to throw up with this ***as a child***? no / yes

How often did you feel sick ***in the past 12 years*** in

	t 0 1 2 3 .
cars	n.a. / never / seldom / sometimes / often
busses	n.a. / never / seldom / sometimes / often
trains	n.a. / never / seldom / sometimes / often
aircraft	n.a. / never / seldom / sometimes / often
small boats	n.a. / never / seldom / sometimes / often
large ships	n.a. / never / seldom / sometimes / often
swings	n.a. / never / seldom / sometimes / often
merry-go-rounds	n.a. / never / seldom / sometimes / often
leisure park attractions	n.a. / never / seldom / sometimes / often

Did you ever have to throw up with this ***in the past 12 years***? no / yes

Thank you for your cooperation.

Reference: Golding, JF. 1998. Motion sickness susceptibility questionnaire revised and its relationship to other forms of sickness. Brain Research Bulletin 47(5):507-16.

Annex F: NATO Questionnaire - Symptoms and Performance (page 1 of 2)

Symptoms

Date _____ Time _____

Location _____

Tasks _____

Sleeping problems before this session

0 = none, 3 = severe: 0 1 2 3

quality of sleep was poor .....
amount of time sleeping was short .....

sleep problems caused by:
- ship motions (bouncing around) .....
- seasickness .....
- other: _____

Symptoms experienced during this session

0 = none, 3 = severe: 0 1 2 3

mental fatigue .....
physical fatigue .....
sleepy .....
headache .....
apathy (just don't care) .....
tension / anxiety .....
vomiting or retching .....
nausea (not vomiting ... yet) .....
stomach awareness .....
other: _____

How seasick are you ? 0 = feel fine, 10 = feel awful

☺ ☹

0 1 2 3 4 5 6 7 8 9 10

Are you taking seasickness medicine ? yes no

Did you vomit before/during this session? yes no

if yes, at about what time ? _____

how did you feel after ? better same worse

Annex F: NATO Questionnaire - Symptoms and Performance

(page 2 of 2)

Performance

Task performance problems during this session

0 = none, 3 = severe:	0	1	2	3
making decisions				
concentration / attention				
memory				
simple tasks (adding, spelling)				
body motions (balance)				
carrying or moving things				
hand coordination				
vision				
other: _____				

Task completion problems during this session

made more mistakes than usual	yes	no
tasks took longer than usual	yes	no
tasks not completed in time available	yes	no
had to abandon tasks	yes	no
not allowed to attempt tasks	yes	no
other: _____	yes	no

Other problems during this session

0 = none, 3 = severe:	0	1	2	3
cold, flu or other illness				
air quality (bad smells)				
noise				
vibration				
lighting (bright , dark)				
temperature (hot , cold)				
other: _____				

Comments _____

_____

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1. ORIGINATOR (the name and address of the organization preparing the document. Organizations for whom the document was prepared, e.g. Centre sponsoring a contractor's report, or tasking agency, are entered in section 8.)

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Protocol for an Experiment on Controlling Motion Sickness Severity in a Ship Motion Simulator

4. AUTHORS (Last name, first name, middle initial. If military, show rank, e.g. Doe, Maj. John E.)

J.L. Colwell

5. DATE OF PUBLICATION (month and year of publication of document)

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32

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Project 11gk

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DRDC Atlantic TM 2004-282

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This protocol defines a human performance experiment to assess the feasibility of controlling the motions of a ship motion simulator (SMS) to achieve a moderate severity of motion sickness, which is sustainable for a substantial time. For this experiment, motion sickness severity is assessed by both the subject and experimenter, and the definition of substantial time is bounded by the two-hour duration of each subject's exposure to motions in the SMS. The secondary goals of this experiment are to examine methods for assessing the effects of moderate levels of motion sickness severity on: (i) the reliability of subjective assessment of task duration, (ii) the reliability of subjective assessment of problems performing cognitive tasks; and, (iii) to explore techniques for assessing problems with complex decision making.

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motion sickness
ship motion simulator
seakeeping
human performance

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